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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,872	03/30/2004	Dominique Charmot	29329-715.202	5573

21971 7590 06/03/2005

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EXAMINER	
HARTLEY, MICHAEL G	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,872	CHARMOT ET AL.	
	Examiner	Art Unit	
	Michael G. Hartley	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/30/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating specific diseases (e.g., hyperphosphatemia), which can be treated by reducing the amount of ions, e.g., phosphate, etc., in the gastrointestinal tract, does not reasonably provide enablement for "treating an animal" as broadly claimed in claim 37. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth hereinbelow.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The claimed invention relates to treating an animal, which encompasses both any animal and any disease. Various diseases having various different causes are not treatable by a single composition.

Given the great diversity between various diseases (viral infections, bacterial infection, cancers, autoimmune diseases, clogged arteries, neurological diseases, etc.), the unpredictability of treating an animal (e.g., no specific disease) has a number of facets, as discussed hereinafter.

A. Treatment of Disease Type

While the state of the art is relatively high with regard to the treatment of specific diseases with a specific agent, it is long underdeveloped with regard to the treatment of an animal broadly, that is, general treatment, with no specific disease combined with a specific drug therefore. In particular, there is no known "treatment" drug, that can treat, "all that ails you". This is why the National Cancer Institute (NCI) has the extensive *in vitro* drug-screening program it does. As discussed by the court in In re Brana, 51 F.3d 1560 (Fed. Cir. 1995), *in vitro* assays are used by NCI (such as the P388 and L1210 lymphocytic leukemia tests at issue therein) to measure the potential antitumor properties of a candidate compound. Brana at 1562-63. If success is shown in this initial screening step, this demonstrates that at least one cancer type (e.g., lymphocytic leukemia) is sensitive thereto, and provides the incentive to select it for further studies to determine its usefulness as a chemotherapeutic agent against other cancer types (lung, breast, colon, etc.) *Id.* at 1567-68. These *in vitro* tests are considered reasonably correlative of success *in vivo*.

Thus, a considerable amount of *in vitro* empirical testing is required, with no *a priori* expectation of success being present, before a candidate for even treating a specific disease, such as, cancer.

B. The therapeutic agent used

Furthermore, the claims do not even have a therapeutic agent. Thus, surely there is no means of treating diseases that require a known drug, such as, the use of an antibiotic, etc.

2. The breadth of the claims

The claims are very broad and inclusive of "treating an animal subject" generally, which includes any treatment. Also, the claims are so broad that they do not include a drug therefor. Clearly, the methods are only used to treat diseases, in which, removal of an ion, such as, phosphate from the gastrointestinal tract, offers some treatment.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction for ascertaining, *a priori*, which diseases can be treated, except those in which removal of an ion from the gastrointestinal tract provides treatment (e.g., hyperphosphatemia, etc.).

4. The quantity of experimentation necessary

The lack of adequate guidance from the specification or prior art with regard to the actual treatment fails to rebut the presumption of unpredictability present in this art. Applicants fail to provide the guidance and information required to ascertain which particular disease the claimed agent will be effective against without resorting to undue experimentation. Applicant's limited disclosure of the treatment of is not sufficient to justify claiming all treatment broadly.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-21 and 25, 26, 31, 32 and 36-44 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Tyler (US 2004/0166156).

Tyler discloses a particle (tablet) comprising a core and a shell material (i.e., coating), see abstract. The particles target a solute as claimed, as they are for lowing serum phosphate level in a patient, removing phosphate from the gastrointestinal tract, see page 1. The core includes the same

polymers as claimed, e.g., polyallylamine, etc. which may be crosslinked with the same crosslinking agent as claimed, e.g., epichlorohydrin, etc,, see pages 1-2 and page 2 [0019]. The cores include a non-metal material. The coating or shell material includes various polymers, including cellulose, etc., see page 2 [0013]. The coating would be physically attached to the core, as it is coated thereon. The particles would inherently be expected to satisfy the functional limitations set forth in the claims, since the particles contain the same components, i.e., the same core polymer and are used for the same purpose. Same compositions must have the same properties. The particles are used for therapeutic methods, including removing toxins, by lower phosphates (to treat renal failure) and lowering cholesterol, see page 1.

Claims 1-21, 25, 30-32, 34 and 36-44 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Simon (US 2005/0036983).

Simon discloses a particle (bead) comprising a core and a shell material (i.e., coating), see abstract, page 3 and example 1. The particles target a solute as claimed, as they are for removing toxins from the body, including urea, etc., see page 3 [0020]. The core includes the same polymers as claimed, e.g., polyallylamine, etc. which may be crosslinked with the crosslinking agents, see pages 3-4 [0020-0030]. The cores include a non-metal material, e.g., polymer as claimed. The coating or shell material includes various polymers, including cellulose, etc., as well as, crosslinked methacrylate polymers, as claimed, see page 4 [0031]. The coating would be physically attached to the core, as it is coated thereon. The particles would inherently be expected to satisfy the functional limitations set forth in the claims, since the particles contain the same components, i.e., the same core polymer and are used for the same purpose. Same compositions must have the same properties. The particles are used for therapeutic methods, including removing toxins, urea, creatinine, etc, see example 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-21 and 25-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Tyler (US 2004/0166156) or Simon (US 2005/0036983) in view of Holmes-Farley (US 5,677,775).

Tyler and Simon disclose particles comprising a core and a shell material (i.e., coating), as set forth above. The core includes the same polymers as claimed, e.g., polyallylamine, etc. which may be crosslinked, as set forth above.

Tyler and Simon fail to specifically recite all the same crosslinking agents for the polymers, as claimed, e.g., diglycidyl ether of bisphenol A, dichloropropane, etc.

Holmes-Farley discloses compositions for the same use as Tyler and Simon, e.g., oral compositions for phosphate binding and teaches the use of the same polymers in the compositions, see column 2. Holmes-Farley further teaches that the same polymers may crosslinked using effective crosslinking agents therefore, which include those claimed, see column 5.

It would have been obvious to use the specific crosslinking agents claimed, as the crosslinking agents for the core materials used in Tyler and Simon, because Holmes-Farley specifically teaches that these crosslinkers are especially useful for crosslinking the same polymers as Tyler and Simon for compositions for the same use. Further, Tyler even incorporates by reference the crosslinked polymers of the Holmes-Farley patent, clearly showing that the use of the crosslinkers of this patent are useful as the crosslinkers of the invention. The crosslinking agents would be applicable to both the shell material and the core material, including the methacrylate polymers disclosed by Simon, which would arrive at claims 29, 30 and 33, which limit the crosslinkers used to prepare the shell material (e.g., acrylates).

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Tyler (US 2004/0166156) or Simon (US 2005/0036983) in view of both Bandi (US 4,902,501) and Kataoka (US 6,881,484).

Tyler and Simon disclose particles comprising a core and a shell material (i.e., coating), as set forth above.

Tyler and Simon fail to specifically recite all the same sizes and shell thickness for the particles, as claimed.

The size of particles and their shell thickness for pharmaceutical use is known to vary depending on the various desired properties.

Bandi teaches particles for the same use as Tyler and Simon and teaches that the particles may have a size of 5 micron, of 500 um as claimed, see column 2.

Kataoka teaches shell-core particles for pharmaceutical use that employ the same polymers as claimed, see column 3. Kataoka teaches particles sizes and a shell thickness may vary and be optimized and teaches sizes and thickness that are within the claimed range, see column 3, lines 45+.

It would have been obvious to optimize the size of the particles disclosed by Tyler and/or Simon to be within the claimed range because it is known in the art that particles size and shell thickness may be optimized to include the ranges as claimed to optimize various desired properties of the particles (disintegration times, amount of polymer, etc.), as shown by Bandi and Kataoka.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael G. Hartley
Primary Examiner
Art Unit 1618

5/26/2005